

Patent

REMARKS

Claims 1-4, 6, and 13-18 are currently pending in this application. Claim 5 and 7-12 have been canceled. Claims 1, 2, 4 and 13 have been amended. New claims 14-18 have been added. No new matter has been added by these amendments or additions. Applicant has carefully reviewed the Office Action and respectfully requests reconsideration of the claims in view of the remarks presented below.

Claim Objections

Claim 5 was objected to under 37 C.R.F. §1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 5 has been cancelled.

35 U.S.C. § 103 Rejections

Claims 1, 5-6 and 13 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication 2005/0065443 (Terne) in view of U.S. Patent No. 4,872,459 (Pless).

Independent claims 1 and 13 relate to implantable cardiac devices and methods employing such devices that determine a maximum heart rate of a patient during exercise. While "implantable cardiac device" is recited in their respective preambles, each of claims 1 and 13 has been amended to further recite "implantable cardiac device" in other claim elements in order to emphasize the implant aspect of the invention. For example, claim 1 recites in part, identifying a heart rate as the maximum observed heart rate using an implantable cardiac device and storing the identified maximum observed heart rate in the implantable cardiac device, when the following conditions occur: (i) the activity level exceeds an activity threshold, (ii) a heart rate measurement is greater than a stored heart rate measurement, and (iii) a difference between the heart rate measurement and the stored heart rate measurement does not exceed a predetermined threshold.

Terne was cited for disclosing features corresponding to claimed features (i) and (ii), while Pless was cited for disclosing feature (iii). Terne discloses a system

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that collects raw heart-rate data over a period of time in response to heart rate or sensor activity. The raw data is then displayed on an external device in a format that allows for observation and extraction of particular heart rate information. While Ternes generally discloses the use of an implantable medical device to collect and process heart-rate data (see paragraphs [0034] and [0042]), it does not disclose an implantable cardiac device, which by itself identifies a heart rate as a maximum heart rate in accordance with the three prerequisites recited in claims 1 and 13. The Ternes system requires the collection of raw data for a period of time and then external observation and external processing of the collected heart rate data in order to identify a maximum heart rate. In addition, because Ternes requires external processing to identify a maximum heart rate, it cannot and does not disclose the storage of an identified maximum heart rate in an implantable cardiac device, as further recited in claims 1 and 13.

Pless discloses a pacemaker algorithm that detects pace-terminable tachycardia conditions in the atrium of the heart in accordance with various criteria, including selected rate stability criteria. Pless is not concerned with determining a maximum heart rate of a patient. Furthermore, it is worth noting that the "pace-terminable tachycardias" identified by the Pless device specifically exclude heart rhythms that occur as a result of exercise. See column 4, lines 42-44. Accordingly, Applicant submits that one of ordinary skill in the art, faced with the task of determining a maximum heart rate of a patient during exercise using an implantable medical device, would not have been motivated to combine the external processing system of Ternes with the tachycardia detection device of Pless, as suggested by the Examiner.

In view of the foregoing, Applicant submits that neither Ternes nor Pless, either alone or in combination, teach or suggest the identification and storage of a maximum heart rate by an implantable medical device, as claimed in independent claims 1 and 13. Accordingly, Applicant requests reconsideration of the §103 rejections of claims 1 and 13 and their respective dependent claims.

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Allowable Subject Matter

Claims 2-4 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims. Claim 2 has been rewritten in independent form including its base claim 1. Claim 4, originally dependent on claim 2, has also been rewritten in independent form including its base claim 1, but not including previously intervening claim 2. Claim 4 is believed to be allowable in this form.

New Claims 14-18

New device claims 14 and 15 correspond to method claims 2 and 4, respectively, and are believed to be allowable for the same reasons as claims 2 and 4.

New claims 16-18 relate to a method of determining a maximum observed heart rate of a patient during exercise using an implantable cardiac device. Current heart rate measurements and current activity level measurements are produced using the implantable cardiac device and compared to a stored heart rate and an activity threshold. The difference between the current heart rate measurement and the stored heart rate measurement are compared to a predetermined threshold. If the current activity level exceeds the activity threshold, the current heart rate measurement is greater than the stored heart rate measurement, and the difference between the current heart rate measurement and the stored heart rate measurement does not exceed a predetermined threshold, the current heart rate measurement is stored as the maximum observed heart rate measurement.

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CONCLUSION

Applicant respectfully submits that the present application is in condition for allowance. If the Examiner believes a telephone conference would expedite or assist in the allowance of the present application, the Examiner is invited to call Steven M. Mitchell at (408) 522-6101.

Pursuant to 37 C.F.R. 1.136(a)(3), Applicant hereby requests and authorizes the U.S. Patent and Trademark Office to (1) treat any concurrent or future reply that requires a petition for extension of time as incorporating a petition for extension of time for the appropriate length of time and (2) charge all required fees, including extension of time fees and fees under 37 C.F.R. 1.16 and 1.17, to Deposit Account No. 22-0265.

Respectfully submitted,

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By:   
Steven M. Mitchell  
Attorney for Applicant(s)  
Reg. No. 31,857

Customer Number: 24473